REMARKS

In the aforesaid Office Action, the claims were subject to restriction, claims 1-9, 11, 14, and 22 were rejected under 35 U.S.C. § 102(e) as being anticipated by Okuda et al. (U.S. Patent No. 6,053,939), claims 1-9 and 14 were rejected under 35 U.S.C. § 102(e) as being anticipated by Zhong (U.S. Patent No. 6,099,563), claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Okuda et al. and over Zhong, claims 12, 13, 15, 16, and 19-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Davis-Lemessy et al. (U.S. Patent No. 6,139,525) in view of Zhong, claims 15, 17, 18 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Campbell et al. (U.S. Patent No. 5,752,934) in view of Zhong. Claims 1-32 are cancelled, and new claims 33-41 are added by this amendment.

The Examiner required a restriction to one of the following inventions under 35 U.S.C. § 121:

I. Claims 1-22, drawn to a medical device

II. Claims 23-32, drawn to a method of coating a medical device.

Applicants hereby affirm election of the invention of Group I, original claims 1-22, drawn to a medical device.

Applicants have added new claims 33-41 directed to a balloon catheter having a multilayered balloon with a polymeric first layer having a plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer, and a polymeric second layer bonded to the section of the first surface of the first layer. Support for new claims 33-41 can be found on pages 15-17.

The Examiner rejected claims 12, 13, 15, 16, and 19-21 (directed to a catheter) under

35 U.S.C. § 103(a) as being unpatentable over Davis-Lemessy et al. in view of Zhong, and claims 15, 17, 18 and 21 (directed to a catheter) under 35 U.S.C. § 103(a) as being unpatentable over Campbell et al. (U.S. Patent No. 5,752,934) in view of Zhong, stating that Zhong discloses bioactive substrate coating for medical devices which enhances the antithrombogenic nature of such devices and renders them biocompatible, and that accordingly, it would have been obvious to one having ordinary skill in the art to coat the catheters of Davis-Lemessy and Campbell et al. with a covalently bonded functionality given that Zhong specifically teaches that doing so would render the catheter antithrombogenic and biocompatible.

However, the combination of Davis-Lemessy et al. or Campbell et al. in view of Zhong does not disclose or suggest a catheter multilayered balloon with a polymeric first layer having a plasma polymerized functionality covalently bonded to at least a section of a first surface of the first layer, and a polymeric second layer bonded to the section of the first surface of the first layer. Instead, Zhong discloses bioactive substrate coatings on an exposed, outer-most surface of the substrate. In contrast, Applicants' claims require that the plasma polymerized functionality is on a surface of a layer of the balloon which is bonded to, and thus covered by, a second layer of the balloon. In Zhong, the bioactive coating enhances antithrombogenicity/biocompatibility of the device. Therefore, there is no teaching or suggestion to provide the bioactive coating on a surface of a balloon layer which is bonded to, and thus covered by, a second layer of the balloon because to do so

would not enhance the biocompatibility of the device (since the surface is not an exposed portion of the device). Therefore, the combination of Davis-Lemessy et al. or Campbell et al. in view of Zhong at most only teaches coating the outer, exposed surface of the balloon of Davis-Lemessy et al. or Campbell et al. with the bioactive, antithrombogenicity/biocompatibility enhancing coating of Zhong.

Moreover, claim 41 calls for a plasma polymerized film having a thickness of about 10 to about 150 nm, which is not disclosed or suggested by the references. The Examiner states that it would have been obvious to one having ordinary skill in the art to optimize the thickness of the covalently bonded functionality given that the thickness of the grafted layer can be controlled by controlling the amount of crosslinking agent present in the solution. However, Applicants can find no teaching or suggestion in Zhong that the thickness of the grafted layer can be controlled by controlling the amount of crosslinking agent present in the solution, or more specifically that the thickness could be limited to the 10 to 150 nm range thickness using the dipping or spraying methods taught by Zhong for applying the coating.

The Examiner rejected claims 1-9, 11, 14 and 22 under 35 U.S.C. § 102(e) as being anticipated by Okuda et al., claims 1-9 and 14 under 35 U.S.C. § 102(e) as being anticipated by Zhong, and claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Okuda et al. and over Zhong. Applicants have cancelled claims 1-11, 14 and 22.

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO/SB/08A; and request that they are considered by the Examiner. This

Information Disclosure Statement is being submitted under 37 CFR §1.97 (c)(2), and therefore the fee set forth in §1.17(p) is due.

Applicants also wish to remind the Examiner of the telephonic conversation with the undersigned on August 27, 2002, in which the Examiner confirmed that the period of reply had been set for the usual three (3) months rather than the one (1) month that was inadvertently marked on the Office Action Summary.

In light of the above amendments and remarks, applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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